



*Via Hand Delivery*

June 20, 2000

Jere Walton Grover  
Chief Counsel for Advocacy  
Small Business Administration  
409 Third Street, S. W.  
Washington, D. C. 20416

**Re: Office of Advocacy Activities with Respect to the Home Care Industry**

Dear Mr. Glover:

The American Association for Homecare (AAH) is pleased to provide the following comments on the health care issues that have been recently addressed by the Small Business Administration's (SBA's) Office of the Chief Counsel for Advocacy (Office of Advocacy). AAH was created by the merger earlier this year of the home care section of the Health Industry Distributors Association (HIDA), the Home Health Services and Staffing Association (HHSSA), and the National Association for Medical Equipment Services (NAMES). AAH represents all segments of the home care industry, including suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health agencies. Our members are mostly small businesses who serve patients in their homes. A significant number of the patients served by AAH members are Medicare beneficiaries who are elderly, frail and sick.

On August 5, 1997, President Clinton signed into law the Balanced Budget Act (BBA) of 1997. This legislation contained numerous provisions that required the Health Care Financing Administration (HCFA) to implement a number of cost cutting measures directed at providers and suppliers of home care services and equipment. AAH members

were directly and significantly impacted by these provisions. The BBA created new Medicare payment methodologies for home health agencies (HHA's) and included a requirement that HHA's obtain surety bonds in order to bill the Medicare program. The BBA also expanded HCFA's "inherent reasonableness" authority to adjust Medicare payment rates for Part B items and services (excluding physician services). HCFA also was given authority to conduct competitive bidding demonstrations for DMEPOS items and services.

The Office of Advocacy officially commented on the small business impact of HCFA's proposals to implement these provisions, including HCFA's adherence to the requirements of the Administrative Procedure Act (APA), the Regulatory Flexibility Act (RFA) and the Paperwork Reduction Act (PRA). In each case, the comments submitted by the Office of Advocacy served to highlight serious procedural and substantive flaws in the manner in which HCFA proposed to implement the BBA requirements. The Office of Advocacy also highlighted the impact these proposals would have on our members, most of which are small business providers and suppliers of home care equipment and services. Our comments on the issues addressed by the Office of Advocacy follow.

### **Inherent Reasonableness**

As we stated above, the BBA expanded HCFA's authority to adjust payment rates for Medicare Part B items and services using inherent reasonableness (IR). While HCFA's IR authority existed pre BBA, the BBA permitted HCFA to make payment adjustments of as much as 15% without using the notice and comment procedures that had been required under the prior law. For payment adjustments greater than 15%, however, the BBA required HCFA to use notice and comment procedures. HCFA chose to implement this extraordinary new authority by publishing an interim final rule rather than a proposed rule as required by the APA. The interim final rule delegated to the Medicare carriers authority to perform IR adjustments of up to 15% a year. Moreover, in the preamble to the interim final rule, HCFA stated that it viewed its expanded IR authority very broadly. According the preamble, HCFA could effect payment reductions greater than the 15% limit in the BBA, provided it implemented the reduction in 15% or less increments over a number of years.

The Office of Advocacy filed comments in 1998 raising numerous procedural flaws in the manner HCFA chose to implement its IR authority. The comments addressed HCFA's failure to publish a notice of proposed rulemaking (NPRM) as required by the APA. As the comments made clear, there were no legal grounds to justify this "procedural shortcut." HCFA's actions circumvented the public debate on a significant expansion of HCFA's authority. Equally important, because the RFA does not apply to interim final rules, HCFA avoided performing an RFA analysis. The Office of Advocacy's comments raised the level of the debate over the procedural fairness of HCFA's actions and the consequences for small business healthcare entities and the Medicare beneficiaries they serve. Last year, Congress asked the Comptroller General to review HCFA's actions with respect to IR. That report is expected this summer.

## **Competitive Bidding**

As we noted above, the BBA also authorized HCFA to conduct "competitive" bidding demonstrations for DMEPOS items and services. The first demonstration began in Polk County, Florida on October 1, 1999. A second demonstration is scheduled to begin in San Antonio, Texas on January 1, 2001. Prior to the effective date of the Polk County demonstration, the Office of Advocacy effectively voiced its concerns about the impact of the demonstration design on small business DMEPOS suppliers. Importantly, HCFA requested expedited review under the PRA of the bidding forms that it proposed to use in the demonstration even though it could not meet the threshold requirements for expedited PRA review. In comments filed with the Office of Management Budget (OMB), the Office of Advocacy noted that HCFA was again avoiding the important debate on the consequences of its actions. The Office of Advocacy also participated in meetings with OMB, HCFA, and industry representatives during which HCFA publicly responded to industry concerns.

## **HHA Surety Bonds**

The Office of Advocacy was instrumental in highlighting that the implementation of the HHA surety bond requirement under the BBA was onerous on HHA's. In its comments, the Office of Advocacy raised concerns about the additional regulatory requirements placed on HHA's by HCFA's interpretation of the BBA surety bond provisions. Those concerns were later realized, as HHA's, the majority of which qualify as small businesses, were unable to secure a surety bond for their business. The regulation was suspended until an in-depth review could be done on the additional requirements. The regulation is expected to go into effect this fall, and include many of the recommendations of the SBA.

## **Other Regulatory Initiatives**

### **Tuberculosis**

The Office of Advocacy provided extensive support to the home health industry on the Occupational Safety and Health Administration (OSHA) tuberculosis proposed rule. The proposed rule highlighted the dramatic decrease in the numbers of tuberculosis reported across the country. OSHA, however, stated that the regulation was still needed for "a potential threat" in later years. The Office of Advocacy was effective in highlighting the changes undertaken by all health care providers to ensure proper treatment of tuberculosis outbreaks. Its comments also emphasized that the result of those changes were the reason for the decline in the number of TB cases. The Office of Advocacy formed an invaluable coalition of health care providers who provided a strong united front on the issue of further requirements on TB. The proposed rule may be released later this year with changes.

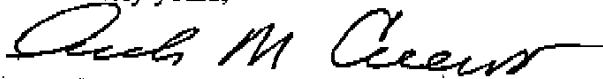
## Ergonomics

The Office of Advocacy also provided support for the home care industry's concerns with the Ergonomics program proposed by OSHA. The Office of Advocacy raised the concern that the cost of the proposed regulation is underestimated, and that the burden of multiple regulations on an industry must be considered before mandating new ones. The Office of Advocacy is recommending regulatory guidance and outreach as an alternative to the costly proposed ergonomic requirements. Hearings on the proposed ergonomics regulation are scheduled to conclude in July, and a final rule could be published as early as this fall.

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We hope that you find the forgoing comments a useful summary of the comments and activities of the Office of Advocacy with respect to providers and suppliers of home care services and equipment. Please feel free to contact me at (703) 836- 6263 should you have any further questions.

Sincerely yours,



Asela M. Cuervo

Vice President for Government Affairs